DEC - 9 2003

PHILIPS

Philips Medical Systems Nederland B.V.

510(k) Summary

K033737

The following information is being submitted in accordance with the requirements of 21 CFR 807.92.

Company Name:	Philips Medical Systems North America Company
Address:	22100 Bothell Everett Highway P.O.Box 3003 Bothell, WA 98041-3003, USA
Registration No.:	1217116
Contact Person: Telephone No.:	Lynn Harmer (425) 487-7312
Date Prepared:	November 18, 2003
Device (Trade) Name:	Allura Xper FD20
Classification Names:	Stationary X-ray system, 21CFR892.1680, Class II (code 90KPR) Angiographic X-ray system, 21CFR892.1600, Class II (code 90IZI)

Predicate Device:
The Allura Xper FD20 is substantially equivalent to the Integris Allura, both manufactured by Philips Medical Systems. The Philips Integris Allura received a 510(k) substantially equivalent determination in K002016 on September 6, 2000.

Device description:
The Allura Xper FD20 is a stationary fluoroscopic angiographic X-ray system for vascular, neurovascular and cardiovascular procedures, as well as non-vascular procedures.

Intended use:
The Allura Xper FD20 is intended for:

- Dedicated vascular and neurovascular imaging applications, including diagnostic and interventional procedures. This includes, e.g., peripheral, cerebral, thoracic and abdominal angiography, as well as PTCAs, stent placements, embolisations and thrombolysis.
- Cardiac imaging applications including diagnostics, interventional procedures (such as PTCA, stent placing, atherectomies), pacemaker implantations, and electrophysiology (EP).
- Non-vascular interventions such as drainages, biopsies and vertebroplasties procedures.

General Safety and Effectiveness information:
The device and their labeling will comply with the applicable requirements of:

- 21CFR, Subchapter J - Radiological Health, parts 1010, 1020.30, 1020.32 & 1040.10.
- Underwriters Laboratories Standard for Safety UL 2601-1 and be classified by Underwriters Laboratories.
- ACR/NEMA DICOM digital imaging communication standard.

Conclusion:
The Allura Xper FD20 does not introduce any new indications for use, nor does the use of the device result in any new potential hazard. Philips Medical Systems considers the Allura Xper FD20 to be substantially equivalent with the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 9 2003

Philips Medical Systems
North America Company
% Mr. John C. So
Senior Project Engineer
Underwriters Laboratories, Inc.
6200 NW Lake Rd.
CAMAS WA 98607

Re: K033737
Trade/Device Name: Allura Xper FD20
Regulation Number: 21 CFR 892.1600
Regulation Name: Angiographic x-ray system
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: 90 IZI and KPR
Dated: November 26, 2003
Received: November 28, 2003

Dear Mr. So:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K033737

Device name: **Allura Xper FD20**

Indications for use:

The Allura Xper FD20 is intended for:

- Dedicated vascular and neurovascular imaging applications, including diagnostic and interventional procedures. This includes, e.g., peripheral, cerebral, thoracic and abdominal angiography, as well as PTCAs, stent placements, embolisations and thrombolysis.
- Cardiac imaging applications including diagnostics, interventional procedures (such as PTCA, stent placing, atherectomies), pacemaker implantations, and electrophysiology (EP).
- Non-vascular interventions such as drainages, biopsies and vertebroplasties procedures.

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K033737

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The counter Use_____
(Per 21CFR801.109)